

**REMARKS**

In the Office Action dated May 2, 2006, claims 1-4, 6, 7, 9-12 and 14, in the above-identified U.S. patent application were rejected. Reconsideration of the rejections is respectfully requested in view of the above amendments and the following remarks. Claims 1, 3-4, 6, 7, 9-12 and 14 remain in this application, claim 2 has been canceled and claims 5, 8, 13, and 15-24 have been withdrawn. This supplemental response is being filed because the withdrawn claims were not indicated as withdrawn in the listing of claims in the response filed on September 5, 2006. All of the amendments and arguments made in this supplemental response are the same as the response filed on September 5, 2006.

The drawings were objected to as duplicated in the tables and sequence listing. Applicants point out that figure 1 shows more than simply a protein sequence. Figure 1 also shows the positions of plasmids and thus deleting this figure would delete information which is not present in the tables and sequence listing. In view of this, applicants request that this objection be withdrawn.

The disclosure was objected to as lacking SEQ ID NOS. The specification has been amended to recite the appropriate sequence identifiers.

Claims 1-4, 9-11 and 14 were rejected under 35 USC §102(b) as anticipated by Hashida. The claims have been amended to indicate that the first antigen comprises multiple epitope regions which are identical in amino acid sequence. As shown in figure 5 of Hashida, the different antigens are used separately. Hashida discloses an antigen by which binding to the solid phase is mediated by DNP and by anti-DNP antibodies

bound to the solid phase. This system is used for a completely different reason (transfer of the formed immune complexes to a further solid phase). The present invention describes the sensitive determination of antibodies particularly of IgM antibodies in the course of infection with HIV and HCV. The advantageous use of multimeric antigens in the determination site is explained in the paragraph bridging pages 4 and 5 of the present specification. The advantages of this determination method can be found in the examples (see page 38, first paragraph, wherein it is shown that the multimeric detection antigens have a factor of differentiation of 19 and 7 respectively, this factor is also improved in the case of multimeric solid phase antigens but only by a factor of 4 and 3, respectively). The advantageous use of multimeric detection antigens can also be deduced from Example 6 (see figure 2). Multimeric detection antigens also have advantages in terms of storage stability (see example 9). In view of the fact that Hashida neither suggests nor discloses the use of multimeric antigens in the determination site (i.e. the use of at least two identical peptides conjugated to the same carrier) as in the present invention, applicants request that this rejection be withdrawn.

Claims 1-4, 9-12 and 14 were rejected under 35 USC §103(a) as unpatentable over Hashida and Formoso. As discussed above, Hashida does not suggest or disclose 2 or more identical peptides conjugated to the same carrier. Formoso does not cure this deficiency as Formoso is cited only for the disclosure of peptide sequences with 6-50 amino acids. Formoso does not disclose an antigen with multiple identical epitope regions. Since neither Hashida nor Formoso discloses an antigen with at least two identical peptides conjugated to a carrier, applicants contend that the presently claimed

invention is patentable over the combination of Hashida and Formoso and request that this rejection be withdrawn.

Claims 6-7 were rejected under 35 USC §103(a) as unpatentable over Hashida and Formoso in view of Watts. Watts was cited for the disclosure of digoxigenin and antidigoxigenin antibody in binding assays. Watts does not disclose an antigen with multiple identical epitope regions and thus does not cure the above discussed deficiencies in Hashida and Formoso. The presently claimed invention uses an antigen with several identical epitope regions which improves the sensitivity of the test. Since neither Hashida, Formoso, nor Watts disclose the use of identical epitope regions, applicants contend that the presently claimed invention is patentable over the combination of Hashida, Formoso and Watts and request that this rejection be withdrawn.


Claims 1-7, 9-12 and 14 were rejected under the judicially created doctrine of obviousness type double patenting over claims 1-7, 9-12 and 14 of U.S. Patent No. 6,613,530. A terminal disclaimer was attached to the response filed on September 5, 2006. In view of the terminal disclaimer, applicants request that this rejection be withdrawn.

Applicants respectfully submit that all of claims 1, 3-4, 6, 7, 9-12 and 14 are now in condition for allowance. If it is believed that the application is not in condition for allowance, it is respectfully requested that the undersigned attorney be contacted at the telephone number below.

In the event that this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fee for such an extension together with additional fees that may be due with respect to this paper may be charged to Counsel's Deposit Account No. 02-2135.

Respectfully submitted,

By



Monica Chin Kitts  
Attorney for Applicant  
Registration No. 36,105  
ROTHWELL, FIGG, ERNST & MANBECK  
1425 K. Street, Suite 800  
Washington, D.C. 20005  
Telephone: (202) 783-6040

MCK/CG